

REMARKS

The Office Action has been carefully considered. The application is believed to be in condition for allowance in view of the following comments.

In the Advisory Action of July 26, 2000, the Examiner has acknowledged that Applicant has shown unexpected results over the use of tap water alone., However, evidence must be shown to prove that Applicant's invention is unexpected over the prior art solutions disclosed in the Develter '226 patent and the Merciadetz et al. '902 patent.

Applicant has filed this CPA and submitted a Declaration under 37 CFR 1.132 which as been found to overcome both rejection of claims 1 and 2 based upon Merciadetz et al. '902 and Develter '226.

Reference is hereby made to *In re Soni*, 34 USPQ2d 1684. In this case, the U.S. Court of Appeals Federal Circuit reversed the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences. In this decision, the majority opinion held that the specification contained more than mere argument or conclusory statements of new and unexpected results; it contained specific data indicating improved properties. Judge Michel wrote a dissenting opinion. In this dissenting opinion, it is stated that one way for an Applicant to satisfy the burden of coming forward with evidence to rebut the prima facie case of obviousness is to demonstrate that the claimed invention yields unexpected results. It was Judge Michel's opinion that Soni had failed to come forward with factual evidence tending to establish the unexpected results. Judge Michel points out that Soni had failed to establish a baseline of expected results against which to measure the observed improvements. It was Judge Michel's position that, without such a baseline, unexpected results cannot be proven. Applicant has provided a baseline showing what one having ordinary skill in the art would expect when ungalvanized nails are placed in tap water alongside the evidence showing the new and unexpected results that are obtained as a result of his invention. Thus, it is submitted that both the majority and the dissenting minority in the *Soni* Court would find in favor of Applicant in this application.

In this application, Applicant has established a baseline. He has shown through demonstrated evidence what is expected when ungalvanized nails are placed in tap water. He has shown by comparative test that what is expected in the baseline tap

water does not occur when ungalvanized nails are placed in his solution. Applicant has further provided demonstrated evidence that the expected results not only occur in tap water, but also occur when ungalvanized nails are placed in the solutions containing potassium sorbate of the two applied references. Applicant has undertaken considerable effort and expense to run, record and provide the results of these latter tests. There are virtually thousands of solutions that contain potassium sorbate in the patent and technical publications. It is unreasonable to expect Applicant to provide proof that his new and unexpected result does not occur in the thousands of potassium sorbate solutions. Applicant should not be expected to undertake such an overwhelming burden to prove the worth of his invention.

Claims 1 and 2 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 5,965,549 to Purwar et al. Reconsideration of this rejection is hereby solicited.

The Purwar et al. Patent No. 5,965,549 (the '549 patent) is directed to a "Ciprofloxacin-Hydrocortisone Suspension" that is intended to be used as an anti-bacterial or anti-inflammatory application. There is no suggestion or teaching whatsoever in this reference that the solution could be used for the prevention of rust and corrosion.

In column 1 of the '549 patent, under the heading "FIELD," it clearly states that this invention relates to compositions and methods for treating external and middle ear infections. Continuing in column 1 under the heading "BACKGROUND," the current methods of treatment of external and middle ear infections are discussed. These methods generally involve the systematic use of antibiotics, particularly ear drops, and mentions that Ciprofloxacin has been used in the treatment for middle ear infection.

In column 2 under the heading "SUMMARY," the invention of this patent is summarized as the provision of a non-ototoxic, non-irritating and non-sensitizing composition for introduction into human and animal ears for the treatment of otitis external and otitis media, particular otorrhea. It is stated in the SUMMARY that potassium sorbate is used in an amount effective as a preservative against contamination by microorganisms. It is noted that the chemical polysorbate is used

and discussed in the SUMMARY, particularly polysorbate 20 to 80 in an effective amount for spreading the composition on a hydrophobic skin surface, and water sufficient to produce a liquid composition. Polysorbate is a surfactant and is not related to potassium sorbate.

There is no mention or discussion in the FIELD, BACKGROUND or SUMMARY sections of this patent of the prevention of rust and corrosion.

Column 4 which is under the "DESCRIPTION" section of the patent states that the Ciprofloxacin compound was difficult to preserve and, in line 20, it states that potassium sorbate, sodium benzoate and benzoalcohol were the candidate preservatives. Again, it is clear that potassium sorbate was used only as an antibacterial preservative which is the common use for potassium sorbate and an antibacterial agent in many foods and beverages. Again, there is no mention of the invention relating to the prevention of rust and corrosion on any surface. In column 4, line 40, the amounts of potassium sorbate effective as a preservative for Ciprofloxacin hydrochloride in aqueous solutions is discussed. Again, the relation of potassium sorbate is strictly as a preservative and has no indication of any new invention involving the preventing of rust and corrosion.

In column 5, the required viscosity of the solution is discussed and it is stated that methylcellulose that is commercially available under the trademark METHOCELL A4M from Dow Chemical Company imparted an effective level of viscosity in low concentrations to the preparation. This product is not the same as cellulose, and it is used to augment the viscosity of aqueous solutions of Ciprofloxacin hydrochloride. Thus, the preparation of the Ciprofloxacin was made with methylcellulose to obtain the proper viscosity and the surfactant polysorbate 20 to 80 that is commercially available under the trademark "Tween" from ICI Americas, Inc.

Both methylcellulose and the polysorbate were blended to effectively spread the composition of this invention on a hydrophobic skin surface range from about .01 to about 2 weight percent.

Thus far, through column 5 of this patent there has been no suggestion that this patent in any way relates to the prevention of rust and corrosion on metal.

In column 6, line 13, the word "rust" is used for the first time in this patent. The following is the sentence in which the word "rust" is used:

Glassware and passivated steel vessels and accessories
free of visible iron ion residue such as rust were used
exclusively.

This is clearly a discussion of the precautions that were taken to avoid contamination in the conduction of EXAMPLE 2 and has nothing whatsoever to do with the preparation of this patent having the ability to prevent rust or corrosion. Passivated steel can be stainless steel or other steel that has been treated to become impervious to rust and corrosion. Thus, this discussion relates only to the vessel being used in the laboratory that is initially free of rust and corrosion on its surface, and in no way relates to the composition preventing rust and corrosion on a metal surface.

Column 7 contains discussions of hearing loss in animals as a result of treatment with and without Ciprofloxacin. The effectiveness of blending hydrocortisone for its anti-inflammatory results is also discussed in column 7. However, there is no discussion of the prevention of rust and corrosion.

The major area of discussion in column 8 is the viscosity of Ciprofloxacin hydrochloride and its effect, either desirable or undesirable, for use as a bacteriostat and also its use to suspend hydrocortisone. Various substances are discussed to suspend hydrocortisone and to be mixed with the antibacteriostat Ciprofloxacin. Polyvinyl alcohol and other ionic products are discussed.

Again, there is no discussion of the prevention of rust and corrosion. In the last paragraph of column 8, it is stated that lecithin in a concentration of about 0.15 weight percent enhances the efficacy of polyvinyl alcohol in suspending hydrocortisone in aqueous preparations with Ciprofloxacin hydrochloride and other components. Clearly,

this lecithin was used only to enhance the suspending effect of polyvinyl alcohol and has nothing to do with the prevention of rust and corrosion.

In column 9, two grades of lecithin are discussed, a fully hydrogenated soy lecithin comprising 90% phosphatidylcholine, commercially available under the tradename "Phospholipon 90H" from American Lecithin Company and a soy lecithin, comprising 75% phosphatidylcholine commercially available under the trade name "Lipoid-S75" from Vernon Walden, Inc. An amount of lecithin effective to augment the suspension of hydrocortisone in aqueous compositions with ciprofloxacin hydrochloride and polyvinyl alcohol range from about 0.01 to about 5 weight percent were used. The use of soy lecithin, in this invention, is to increase the suspension of either the alcohol or the hydrocortisone. Again, it has nothing to do with the prevention of rust and corrosion.

Example 5, is discussed in column 10. In this example, they repeat the manufacturing procedure and repeat the above discussion regarding the use of passivated steel vessels and accessories, that are free of visible iron ion residue such as rust. As previously stated, this has nothing to do with the preparation preventing rust. The formulation for Example 5 is provided in Table 2 that is presented in column 11.

Example 6, in column 11 has to do with dispersability and settling test on a specimen of the composition of TABLE 2. Again, has nothing to do with the prevention of rust or corrosion.

Example 8, discussed in column 11, also deals with hearing assessments performed by auditory brain-stem response. These tests were performed on animals and observed daily for clinical signs of systemic toxicity. After 30 days, the middle ear was examined and the results evaluated. Again, this has nothing to do with the prevention of rust and corrosion on metal.

In column 12, Example 9, this composition was determined to be adequately resistant to contamination by microorganisms over a reasonable shelf life. It is stated that, however, a preservative, such as, for instance, potassium sorbate or benzyl alcohol, may be included for added protection. Potassium sorbate has for the past 50 years been used in studies involving inhibition of microorganisms as used in the

examples discussed in this patent. This is the common and well known use of potassium sorbate.

The preamble for claim 1, the only independent claim of this patent states:

An aqueous non-ototoxic, topical, otic pharmaceutical composition of matter for treating a mammal consisting essentially of:

Thus, this patent makes no claims that the preparations disclosed therein have the property to prevent rust, and there is absolutely no basis for the rejection of claims 1 and 2 in this patent. For all of the above reasons, reconsideration and withdrawal of this rejection are respectfully requested.

Thus, Applicant maintains that his invention as set forth in claims 1 and 2 is not disclosed or taught in the prior art references to Purwar et al. The Applicant, therefore, requests reconsideration and allowance of this application.

Respectfully submitted,



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